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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/127,624	08/03/1998	F. ABEL PONCE DE LEON	002076-007	1506

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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/127,624	Applicant(s) Ponce De Leon et al.
	Examiner Michael C. Wilson	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 11, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 4, 5, 7, 8, 30-35, and 37-42* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 4, 5, 7, 8, 30-35, and 37-42* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1632.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-11-02, paper number 24, has been entered.

The amendment filed 1-14-02, paper number 18, has been entered. Applicant's arguments filed therewith have been fully considered but are not persuasive. Claims 29 and 36 have been canceled. Claims 41 and 42 have been added. Claims 1, 4, 5, 7, 8, 30-35 and 37-42 are pending and under consideration in the instant office action. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

The effective filing date for claims 1, 4, 5, 7, 8, 30-35 and 37-42 is 8-4-97.

Claim Rejections - 35 USC § 112

1. Claims 32 and 38 remain rejected and claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of culturing avian PGCs comprising maintaining the avian PGCs for at least 14 days in culture comprising (i) isolating a pure population of PGCs from an avian; and (ii) culturing the pure population of PGCs in media comprising LIF, bFGF, IGF and SCF in amounts sufficient to maintain said PGCs for at least 14 days in tissue culture, does not reasonably provide enablement for culturing the PGCs for at least 14 days in media comprising "growth factors in amounts sufficient to maintain said PGCs for at least 14 days" as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for reasons of record.

The state of the art at the time of filing was that pure populations of avian PGCs had been cultured for 5 days in the presence of exogenous LIF, bFGF and IGF (Chang, 1995, Cell Biol. International, Vol. 19, pages 143-149; page 143, col. 2, 2nd paragraph through page 144, col. 2, 2nd full paragraph). However, a population of avian blastoderm cells comprising PGCs had been maintained for 160 days using exogenous bFGF, IGF, SCF and LIF (Pain of record, page 2340, col. 1, line 9; page 2340, col. 1, 4th and 5th full paragraphs; page 2345, col. 2, line 10; Simkiss of record, 1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137; page 111, Fig. 4.1, top panel).

The specification teaches culturing a pure population of avian PGCs for at least 14 days using growth medium comprising exogenous LIF, bFGF, IGF and SCF. The specification and the art at the time of filing did not teach using feeder cells expressing LIF, bFGF, IGF and SCF in amounts sufficient to maintain a pure population of avian PGCs for at least 14 days.

Claims 32 and 41 are directed toward a method of culturing a pure population of avian PGCs in a culture medium using feeder cells that supply LIF, bFGF, SCF and IGF in amounts adequate to maintain said PGCs for at least 14 days. Claims 38 and 42 are directed toward a purified population of avian PGCs in culture media and feeder cells that supply LIF, bFGF, SCF and IGF in amounts adequate to maintain said PGCs for at least 14 days. Claims 32 and 38 remain and claims 41 and 42 are not enabled as broadly claimed for reasons of record because the specification does not enable providing LIF, bFGF, SCF and IGF in amounts sufficient to maintain said PGCs for at least fourteen days using feeder cells. The only method taught in the specification or the art at the time of filing (Pain of record) that results in maintaining PGCs in culture for at least 14 days requires culture media comprising exogenous LIF, bFGF, IGF and SCF. The specification does not teach any feeder cells that provide the growth factors in amounts sufficient to maintain PGCs for at least 14 days, or how to obtain the amounts required using feeder cells transfected with DNA encoding the growth factors. Applicants argue that the specification contemplates transfecting feeder cells to express the desired growth factors which is adequate to enable using feeder cells to provide exogenous growth factors as claimed (pg 13, lines 10-15). Applicants argument is not persuasive. First, the claims are not limited to

transfected feeder cells. Second, applicants have not provided any evidence (correlative or otherwise) that feeder cells produce the amounts of the growth factors required to have the desired effect. Therefore, the mere statement that cells can be transfected to produce the growth factors required to maintain a pure population of PGCs for at least 14 days is not adequate to enable feeder cells that supply growth factors in amounts that maintain a pure population of avian PGCs for at least 14 days. Applicants provide Slanicka (1998) and Durcova-Hills (1998) which were not available at the effective filing date of the claimed invention, 8-4-97. Thus, given the teachings in the art taken with the guidance provided in the specification, one of skill in the art would not have known how to transfect feeder cells to obtain the amounts of LIF, bFGF, SCF and IGF required to sustain PGCs for at least 14 days as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. New claims 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41 and 42 are indefinite because it is unclear if all of the feeder cells are transfected with DNA encoding at least one of the growth factors or with DNA encoding all of the growth factors. Parent claims 32 and 38 require the feeder cells provide all of the growth

factors, but claims 41 and 42 appear to only require the transfected feeder cells provide at least one growth factor.

Double Patenting

3. Claims 1, 4, 5, 30, 31, 33, 37, 39 and 40 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000 for reasons of record.

4. Claims 1, 4, 5, 7, 8, 30, 31, 33, 34, 35, 37, 39 and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000 in view of Pain (Pain et al., 1996, Development, Vol. 122, pages 2339-2348) for reasons of record. The claim numbers have been changed to include those claims inadvertently omitted. It is readily apparent that claims 4, 5, 30, 31, 37, 39 and 40 should have been included because they are rejected over 6,156,569 alone in the rejection above.

Applicants request to hold the double patenting rejections in abeyance until indication of allowable subject matter is acknowledged; however, failure to either argue this rejection or to indicate willingness to file a terminal disclaimer in response to the instant office action will be considered non-responsive.

5. Claims 1, 4, 5, 7, 8, 30-35 and 37-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-23 and 25-30 of copending Application No. 09/127738 as supported by Pain of record (pg 2340, col.

1, line 9; page 2340, col. 1, 4th and 5th full paragraphs; page 2345, col. 2, line 10) and Simkiss of record (1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137; page 111, Fig. 4.1, top panel). Although the conflicting claims are not identical, they are not patentably distinct from each other because avian embryonic germ cells are a species of avian PGCs as required in the instant claims. In addition, culturing EG cells as required in '738 inherently requires culturing PGCs as claimed in the instant invention and supported by Pain and Simkiss.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER